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| EXAMINER | |
|---|---|
| SPIVACK, PHYLLIS G | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/531,900 | SCHUTZE ET AL. | |
| | Examiner | Art Unit | |
| | Phyllis G. Spivack | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 11-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 11-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-2-07;4/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Preliminary Amendment filed April 21, 2005 is acknowledged. Claims 2-10 are canceled. New claims 11-21 are presented. Accordingly, claims 1 and 11-21 are now under consideration.

Two Information Disclosure Statements filed April21, 2005 and May 2, 2007 are further acknowledged and have been reviewed to the extent each is a proper citation on a U.S. patent.

A new Abstract is noted.

Claim 14 provides for the use of the medicament according to claim 12 comprising tenatoprazole, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The recitation drawn to the treatment of "atypical" symptoms of gastroesophageal reflux renders claim 12 indefinite. Those atypical symptoms contemplated cannot be precisely determined. Applicant should recite those symptoms contemplated.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7 and 9 of copending Application No. 10/561844. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 encompasses a medicament comprising enantiomers of tenatoprazole. The co-pending claims additionally are drawn to an amount of active substance in the range of 10-80 mg and may be employed to treat digestive bleeding.

Claims 1 and 11-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 14-22 of copending Application No. 11/344212. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 encompasses a medicament comprising enantiomers of tenatoprazole. The co-pending claims additionally are additionally drawn to dosage forms and an amount of active substance that overlaps with those presently claimed and are employed to treat any digestive disease.

Claims 1 and 11-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 9-18 of copending Application No. 10/532114. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claims are drawn to compositions comprising tenatoprazole to treat any disease, including symptoms and lesions, relating to gastric hyperacidity. The open language of the present claims allows for the inclusion of any number of additional active or inactive agents.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claims 1 and 11-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-10 and 14-25 of U.S. Patent 7,034,038. Although the conflicting claims are not identical, they are not patentably

distinct from each other because instant claim 1 encompasses a medicament comprising enantiomers of tenatoprazole. The claims additionally are drawn to dosage forms and an amount of active substance that overlaps with those presently claimed and are employed to treat any digestive disease.

Claims 12-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for showing evolution of symptoms and atypical symptoms associated with gastroesophageal reflux disease, does not reasonably provide enablement for treatment of these symptoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

To be enabling, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Circ.1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC

1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547, the court recited eight factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The invention is drawn to the treatment of atypical and esophageal symptoms of gastroesophageal reflux, digestive bleeding, dyspepsia, Barrett's esophagus, nocturnal reflux, pseudo-ulcer dyspepsia, asthma, asthma-like acute dyspnea, pharyngitis,

dysphonia, pseudo-angina, paroxysmal cough and/or nocturnal cough comprising administering tenatoprazole.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. with expertise in the area of gastroenterology.

However, that factor is outweighed by the unpredictable nature of the art. The scope of enablement varies inversely with the degree of unpredictability of the factors involved, and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 166 USPQ 18. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. *Nationwide Chemical Corporation v. Wright*, 192 USPQ 95. One skilled in the chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances, *Ex parte Sudilovsky*, 21 USPQ2d 1702, concerning pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable.

The instant specification on page 8 is drawn merely to a hypothesis that tenatoprazole *can be used* to treat atypical symptoms of gastroesophageal reflux, such as asthma, dyspneic attacks of asthma, pharyngitis, dysphonia, pseudo-angina, paroxysmal cough, nocturnal cough and Barrett's esophagus. Tables 2, 3 and 4, pages 9, 10 and 11, are drawn to "evolution of symptoms" without a clear showing of positive therapeutic effects. Table 5 on page 12 shows "endoscopic improvement ratings"

without showing a nexus to asthma, dyspneic attacks of asthma, pharyngitis, dysphonia, pseudo-angina, paroxysmal cough, nocturnal cough and Barrett's esophagus.

These descriptions are clearly not predictable for treatment of any atypical and esophageal symptom of gastroesophageal reflux disease.

The breadth of the claims

The claims are extremely broad in that multiple pathologies are encompassed in the claim language that are extraesophageal in nature.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples drawn to a treatment modality in which tenatoprazole is clearly shown to be clinically effective for atypical symptoms of gastroesophageal reflux, such as asthma, dyspneic attacks of asthma, pharyngitis, dysphonia, pseudo-angina, paroxysmal cough, nocturnal cough and Barrett's esophagus. An improvement in the symptoms of those patients who are described in the Tables in the specification, having gastroesophageal reflux disease, is unclear.

The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed supra) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that the instantly claimed compound could be predictably used as a treatment for all atypical and esophageal symptoms of gastroesophageal reflux disease.

*Genentech Inc. vs. Nova Nordisk* states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable," 42 USPQ 2d 1001, Fed. Circuit (1997).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 11-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Barth et al., US 2006/0024238.

Barth teaches the administration of one proton pump inhibitor, such as tenatoprazole, or a pharmaceutically acceptable salt thereof, in the treatment of atypical and esophageal symptoms of gastroesophageal reflux disease (GERD). Barth's

teaching encompasses, *inter alia*, treating Barrett's esophagus, horseness, wheezing, coughing and asthma. See paragraphs [0009] and [0010], page 2, [0029], page 4, and **[0044] page 5**, and claims 9, 12-14, pages 13-14. Barth teaches equivalence among the proton pump inhibitors in methods of treating GERD. Dosages, as required by instant claims 11, 15 and 16, are taught to be preferably about 10-30 mg per day, in paragraph [0091], page 9. As required by instant claim 14, injectable preparations are disclosed in paragraph [0096], page 9. Medicaments comprising proton pump inhibitors for oral administration are disclosed in paragraph [0097] on page 10.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 23, 2007

Phyllis G. Spivack
1614

PHYLLIS SPIVACK
PRIMARY EXAMINER